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September 16, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of H. Hofland, D. Lamons, and X. Meng
Application No. 09/996,838
Filed November 29, 2001
Natural and Anionic Colloidal Particles for Gene Delivery

Group No. 1632
Examiner D. Nguyen

(Atty. Docket No. P 23,643-A USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Tuesday, September 16, 2003.

Arlene M. Olson

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME UNDER 37 CFR §1.136(a)

Sir:

It is requested hereby that the term to respond to the Requirement for Restriction, dated July 16, 2003, be extended one month, from August 16, 2003 to

09/25/2003 ANAB11 00000040 09996838

01 FC:1251

110.00 OP

September 16, 2002.

A check to cover the extension fee is enclosed. The Commissioner is authorized hereby to charge any additional fees or credit any overpayment associated with this communication or the accompanying Reply to Deposit Account No. 19-5425. A duplicate of this latter is attached.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Gene J. Yao', is written over a horizontal line.

Gene J. Yao, Esquire

Reg. No. 47,193

Attorney for Applicants

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GJY/amo

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Arlene M. Olson

Commissioner for Patents
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Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION
UNDER 37 CFR §1.143 OF THE EXAMINER'S
REQUIREMENT FOR RESTRICTION, DATED JULY 16, 2003

Sir:

In response to the Examiner's Requirement for Restriction of July 16, 2003, applicants elect, with traverse, the Group II claims (Claims 1, 6 to 11, 14, 15, and

17 to 19), drawn to a process for making neutral or anionic DNA-containing complexes comprising forming a colloid comprising a DNA sequence and a citraconic anhydride and a colloid comprising a DNA sequence and a citraconic anhydride. Applicants note that the Examiner has indicated that the present Requirement would be withdrawn if claims linking the various claim groups are allowed.

Applicants traverse, however, the Examiner's Requirement. It is submitted respectfully that the Examiner's Requirement is deficient on its face because 35 U.S.C. §121 requires that the subject matter of the claim groups be independent from each other, as well as distinct. Clearly, the inventions which are defined in the various groups of claims are not independent in that there exists a disclosed relationship amongst them, as evidenced by the generic claims linking the claim groups. The Examiner has grouped the claims based on whether the colloid recited by the claims includes a poly(alkylene oxide) (Group I), a citraconic anhydride (Group II), or an NHS acetate (Group III). Each of these are compounds which are intended to modify the surface potential of a DNA-containing colloid in order to form a colloid with a neutral or net anionic surface potential. Accordingly, they are all charge modification compounds.

The Examiner has recognized apparently that the claim groups do not define independent inventions because he has not characterized them as being independent. Moreover, the Examiner has not even attempted in his Action to explain why he considers the claims to be directed to independent inventions. Consequently, the Examiner has issued a Requirement that is deficient on its face because he has not explained why the various claims groups are considered to define independent subject matter. Accordingly, the Requirement should be withdrawn.

It is submitted further that the charge modification compounds of the present invention serve the same function in the recited colloid, that of neutralizing or making anionic the otherwise cationic charge of the colloid, and operate by the same means, that being their ability to bind to the cationic lipid or polymer used to bind DNA in the colloid. Accordingly, the Examiner's Requirement with respect to all groups should be withdrawn because it is believed that a proper search of the subject matter of any one of the groups of claims cannot be done except that a search is conducted for the subject matter of all groups of claims. This is so because the subject matter of the claims is so interrelated.

In his Requirement, the Examiner noted that, if any of the above claim groups are elected, applicants must elect a species of the colloid defined therein to which the claims shall be restricted if no generic claim is held to be allowable. According to the Examiner, the species are defined by whether the recited DNA is complexed with a cationic polymer or a cationic lipid.

Applicants elect, with traverse, the species of applicants' invention in which the recited DNA is complexed with a cationic lipid to which the claims shall be restricted if no generic claim is held to be allowable. Claims 1, 6 to 11, 14, 15, and 17 to 19 read on this species. It is submitted respectfully, however, that the cationic lipid and the cationic polymer of the complexes of the present invention serve the same function in the recited colloid, that being the binding of DNA, and operate by the same means, that being their having a charge affinity for the anionic DNA. It appears, therefore, that a proper search of the subject matter of one species of applicants' invention cannot be done except that a search is conducted for the subject matter of all species. This is so because the subject matter of the species is so interrelated. Accordingly, applicants traverse respectfully the Examiner's election of

species requirement.

In view of the foregoing, an early and favorable Action is requested respectfully.

This Request is accompanied by a Petition for Extension of Time to respond to the Examiner's Action.

Respectfully submitted,



Gene J. Yao, Esquire

Reg. No. 47,193

Attorney for Applicants

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